

REMARKS

This Amendment is submitted in reply to the non-final Office action (hereinafter referred to as "Office action") mailed on May 13, 2009. The Office action provided a three-month shortened statutory period in which to respond, ending on August 13, 2009. Accordingly, this amendment is timely submitted. No fees are believed due with this Amendment. The Director is authorized to charge any fees that may be required, or to credit any overpayment to Deposit Account No. 50-4498 in the name of Nestle Nutrition.

Claims 1, 5-8, 10-11 and 26-27 are pending in this application. Claims 2-5, 9 and 12-25 were previously canceled without prejudice or disclaimer. In the Office action, Claims 1, 6-8, 10-11 and 26 are rejected under 35 U.S.C. §112. Claim 27 is rejected under 35 U.S.C. §103. Applicant does not acquiesce in the correctness of the rejections or objections and reserves the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

In response, Claim 27 has been amended. The amendment does not add new matter. The amendment is supported in the specification at, for example, page 10, lines 12-15; Example 2. In view of the amendments and/or for the reasons set forth below, Applicant respectfully submits that the rejections should be withdrawn.

The present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present

invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention.

In the Office action, Claims 1, 5-8, 10-11 and 26-27 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Patent Office alleges that "Applicants do not describe th[e] invention in such a manner that would enable one of ordinary skill in the art to use th[e] invention at the higher claimed range of about 15 to about 20 g [of an oligosaccharide blend] without undue burden." See, Office action, page 3, lines 7-9.

In response, Applicant also notes that compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. An example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. See, MPEP 2164.02. Therefore, Applicant respectfully submits that, even if the Patent Office is correct that there are no working examples that describe the use of from about 15 g to about 20 g of an oligosaccharide blend, such a requirement is not necessary and the present disclosure is still enabling.

More specifically, and with respect to Claims 1, 6-8, 10-11 and 26, Applicant notes that an analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement is whether the experimentation needed to practice the invention is undue or unreasonable. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

Indeed, the Patent Office relies on the eight factors from *In re Wands* to assert that Claims 1, 6-8, 10-11 and 26 are allegedly not enabled. However, Applicant respectfully disagrees with the Patent Office's analysis. For example, with respect to the breadth of the

claims, the Patent Office asserts that the only scope supported by the specification would include "2 g (Example 2), 9.86 g (Example 3), and 2.5 g (Example 4) of fiber (FOS and GOS) in a single composition." See, Office action, page 4, lines 5-8. Regarding the amount of direction provided by the inventor, the Patent Office asserts that "[t]here is nothing in the specification that would indicate that the current invention is capable of working at any amount higher than the 9.86 g of Example 3." See, Office action, page 5, lines 10-12. With respect to the presence or absence of working examples, the Patent Office states that "[t]here are no examples provided of how one would use a composition of an amount above 10g, and certainly not 20g or even 15g and as such these amounts are not supported." See, Office action, page 6, lines 1-3.

However, contrary to the Patent Office's assertion, and as discussed above, the present claims are, in fact, supported by the specification, regardless of whether the scope of the claims is set forth in an example. Applicant initially notes that the Patent Office's statement that "[t]here are no examples provided of how one would use a composition of an amount above 10g, and certainly not 20g or even 15g and as such these amounts are not supported," confuses the written description requirement with the enablement requirement. Indeed, since the specification clearly provides support for 20g or 15g of the oligosaccharide blend, see, paragraph [0040], the claims are clearly "supported" in accordance with the written description requirement. Further, because any skilled artisan would be capable of measuring 20g or 15g of an oligosaccharide blend and adding the blend to a composition, Applicant also respectfully submits that the experimentation needed to practice the invention is not undue or unreasonable.

As discussed above, compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, does not turn on whether an example is disclosed. Indeed, the presence of a working example is just one of at least eight factors to consider when evaluating enablement. Further, an example may be "working" or "prophetic." A working example is based on work actually performed. A prophetic example describes an embodiment of the invention based on predicted results rather than work actually conducted or results actually achieved. An applicant need not have actually reduced the invention to practice prior to filing. See, MPEP 2164.02. Therefore, Applicant respectfully submits that, even if the Patent Office is correct that there are

no working examples that describe the use of from about 15 g to about 20 g of an oligosaccharide blend, the present disclosure is still enabling.

With respect to the state of the prior art, the Patent Office alleges that "[t]he art teaches that a single composition should not contain more than 10 g of fiber and Applicant[']s instant Examples do not contain more than 10g of fiber." The Patent Office also states that "[i]t is clear from the prior art above that amounts in a single composition above 10g give discomfort to a person." See, Office action, page 5, lines 16-22. However, Applicant respectfully submits that the Patent Office mischaracterizes the scope of the prior art.

For example, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention.

Moreover, Applicant respectfully submits that simply because the prior art allegedly discloses that too much fiber may cause discomfort does not make the presently claimed subject matter unpatentable. Applicant notes that the prior art does not disclose or suggest that a specific oligosaccharide blend of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS) may cause discomfort. In fact, the prior art only states that too much fiber may cause discomfort. Such a blanket statement cannot always be true and fails to even consider that there may be combinations of fibers that do not provide discomfort, as is clearly the case with the presently claimed subject matter.

Additionally, the enablement requirement requires only that practicing the claimed invention not be unduly burdensome for the skilled artisan. It does not require that administration of a composition results in no adverse side effects. In fact, many patented drugs, pharmaceuticals and nutritional supplements can cause adverse side effects. Therefore, while Applicant does not admit that administration of the presently claimed compositions may cause discomfort and, in fact, submits that the opposite is true and the presently claimed compositions result in synergistic effects in promoting the growth of beneficial bacteria, Applicant submits that it is irrelevant whether the prior art indicates that more than 10g of fiber may cause discomfort. Indeed, such a teaching would actually lead the skilled artisan down a path divergent from the presently claimed subject matter in view of such a disclosure. Accordingly, the prior art would actually teach away from the presently claimed subject matter.

Finally, with respect to the quantity of experimentation, the Patent Office continues to assert that "a burdensome amount of research would be required by one of ordinary skill in the art to bridge [the] gap" between a composition comprising 2g, 2.5g, and 9.86g and a composition comprising about 25g, about 20g or about 15g of fiber. See, Office action, page 6, line 19-page 7, line 1. However, Applicant respectfully disagrees. Instead, Applicant notes that specific amounts of specific ingredients for use in the present compositions are clearly set forth in the specification. Among those specific amounts of ingredients, a composition comprising from about 15 g to about 20g of fiber is clearly set forth in the specification. According, since the Patent Office admits that the relative skill of those in the art is very high (e.g., Ph.D and M.D. level technology), Applicant respectfully submits that the skilled artisan would be more than capable of measuring from about 15 g to about 20 g of fiber to include in a composition comprising both FOS and GOS in the presently claimed ratios. Indeed, the relative skill of a Ph.D or an M.D. is not even required to be able to create a composition according to the present claims that include from about 15 g to about 20 g of fiber. For at least these noted reasons, Applicant respectfully submits that the present claims are fully enabled by the specification and would not require a burdensome amount of experimentation for the skilled artisan to obtain compositions according to the present claims.

Accordingly, Applicant respectfully requests that the rejection of Claims 1, 5-8, 10-11 and 26-27 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

In the Office action, Claim 27 is rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,399,124 to Lesens et al. ("*Lesens*"). However, Applicant respectfully submits that *Lesens* is deficient with respect to the present claims.

Currently amended independent Claim 27 recites, in part, compositions comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of *Lactobacilli*. The amendments do not add new matter. The amendments are supported in the specification at, for example, page 10, lines 12-15; Example 2.

As discussed above, the present invention specifically describes how the use of high levels of FOS may lead to excessive gas production in human volunteers. To avoid such potential disadvantages of high levels of FOS, the present invention has shown that the prebiotic properties of FOS are significantly improved by the presence of GOS and that the effects of FOS and GOS are more than additive (i.e., a synergistic effect in promoting the growth of beneficial bacteria has been observed). As a result of the synergy, it is possible to obtain an equivalent or improved prebiotic effect of FOS at lower dosages. This has the advantage that a powerful prebiotic effect can be achieved in vivo while avoiding the need to ingest any single prebiotic at levels that could induce side effects. In addition, the maximum prebiotic benefit obtainable is superior to that gained from prebiotics individually. See, specification, page 3, lines 11-26. As such, the present invention considers the disadvantages of providing too much of a certain type of fiber and discusses, in detail, how these disadvantages may be overcome by the present invention. In contrast, Applicant respectfully submits that *Lesens* fails to disclose each and every limitation of the present claims.

Lesens fails to disclose or suggest compositions comprising glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), wherein the weight ratio of FOS and GOS is from about 0.5 to about 20 and wherein the FOS and GOS are capable of synergistically promoting the growth of

Lactobacilli as is required, in part, by Claim 27. Instead, *Lesens* is directed to frozen desserts that contain lactic acid bacteria and dietary fibers and its benefit to the human health after consumption of the frozen desserts. The maximum amount of fibers that make up the edible support of the frozen desserts is 10 g of fiber per dessert. According to *Lesens*, higher quantities of fibers would induce an unpleasant feeling of heaviness in the stomach. See, *Lesens*, col. 5, lines 23-29. As such, the highest amount of fiber that may be attained by the frozen desserts of *Lesens* is about 10 g. This is in direct contrast to the present invention. *Lesens* also fails to disclose or suggest the use of glutamine at any place in the disclosure. Such a bioactive compound is known to have health benefits, especially with respect to the gastrointestinal tract. Further, *Lesens* also fails to disclose or suggest compositions having an oligosaccharide blend consisting essentially of FOS and GOS, as required, in part, by currently amended independent Claim 27. Indeed, the Patent Office even admits that *Lesens* fails to disclose a composition having the specific amounts of the present claims. See, Office action, page 8, line 16.

Instead, the Patent Office asserts that it would have been obvious to one of ordinary skill in the art to make a composition of FOS and GOS in a specific ratio. As support for this statement, the Patent Office asserts that "Examples 4-5 of *Lessens* et al teach a cone made of Raftilose L30 (table 7) or wafer dough of galactooligosaccharide P7L, respectively; and a decoration or coating such as that of Table 3 (galactooligosaccharide P7L) or Table 4 (Raftilose L30). Such a ratio would yield a weight ratio of 1.56 FOS:GOS in the single food composition." See, Office action, page 8, lines 8-12. The Patent Office cites other portion of *Lesens* as disclosing other claimed elements of the present invention. However, Applicant respectfully submits that the rejections are based on a misunderstanding of the disclosure of *Lesens*.

For example, the Examples cited by the Patent Office as disclosing the use of either FOS or GOS do not even use the FOS and GOS in the same compositions, let alone the FOS and GOS used in the same compositions as an oligosaccharide blend. At best, *Lesens* discloses that an aerated ice creams may be dipped into compositions having GOS (Table 3) or FOS (Table 4), or that ice cream may be contained in a wafer dough containing FOS (Examples 4-5) or GOS (Example 5). At no place in the disclosure does *Lesens* disclose the use of FOS and GOS in an oligosaccharide blend. In fact, *Lesens* never discloses that the FOS and GOS are used in the

same composition, let alone as an oligosaccharide blend of a specific amount, or as an oligosaccharide blend consisting essentially of those two oligosaccharides as required, in part, by the present claims.

The Patent Office asserts that “[i]f an applicant contends that additional steps or material in the prior art are excluded by the recitation of ‘consisting essentially of,’ applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention.” See, Office action, page 10, line 21-page 11, line 2. However, in view of the current amendment to Claim 27, Applicant respectfully submits that this assertion is rendered moot since *Lesens* fails to disclose each and every element of the present claims. Specifically, *Lesens* fails to disclose or suggest a composition having glutamine and an oligosaccharide blend that consists essentially of fructo-oligosaccharide (FOS) and galacto-oligosaccharide (GOS), as is discussed above.

Moreover, *Lesens* teaches away from the present claims. As discussed above, *Lesens* discloses that “the dessert may be designed so as to be able to potentially provide up to a maximum of 10 g of fibre per dessert, high quantities of fibers indeed inducing an unpleasant feeling of heaviness in the stomach.” See, *Lesens*, col. 5, lines 23-26 (emphasis added). This is in direct contrast to the present claims, which require, in part, from about 15 g to about 20 g of an oligosaccharide blend of FOS and GOS. Indeed, Applicant respectfully submits that the presence of an “upper limit” of 10 g of fiber per dessert in *Lesens* requires that *Lesens* prohibits the use of any more than the “upper limit.” As such, Applicant disagrees with the Patent Office’s assertion that such an upper limit would not teach the skilled artisan away from the use of fibers that are greater than the upper limit. For at least the above-mentioned reasons, Applicant respectfully submits that not only would the skilled artisan have no reason to modify *Lesens* because *Lesens* teaches away from the present claims, but *Lesens* also fails to disclose each and every element of the present claims.

Accordingly, Applicant respectfully requests that the obviousness rejections of Claim 27 under 35 U.S.C. §103(a) be reconsidered and withdrawn.

Appl. No. 10/721,652

Reply to non-final Office action dated May 13, 2009

For the foregoing reasons, Applicant respectfully requests reconsideration of the above-identified patent application and earnestly solicits an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic interview, the Patent Office is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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